DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 4, 2015

Gardia Medical Ltd.
Ohad Haas
VP Quality Assurance & Regulatory Affairs
2 Ha-Eshel Street, PO Box 3081
Caesarea Industrial Park 38900, Israel

Re: K143570
Trade/Device Name: WIRION
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: May 7, 2015
Received: May 11, 2015

Dear Ohad Haas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143570

Device Name
WIRION™

Indications for Use *(Describe)*

The WIRION™ is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/ debris) while performing angioplasty and stenting procedures in carotid arteries.
The diameter of the vessel at the site of filter basket placement should be between 3.5 mm to 6.0 mm. WIRION™ may be used with commercially available 0.014" guide wires.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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TRADITIONAL 510(K) SUMMARY
WIRION™ Embolic Protection System

Date of summary: June 1, 2015

510(k) Number: K143570

Applicant's Name: Gardia Medical Ltd.
2 Ha-Eshel St. P.O. Box 3081
Caesarea Industrial Park 38900, Israel
Tel.: +972-4-6277166, Ext. 107
Fax: +972-4-6277266

Contact Person: Ohad Haas
VP QA & RA
Phone: (972) 4-6277166, Ext. 303
Fax: (972) -4-6277266
ohadh@gradiamedical.com

Trade Name: *WIRION*™

Common name: Embolic Protection System

Classification: **Name:** Embolic Protection System
Description: Cardiovascular Percutaneous catheter
Product Code: NTE
Regulation Number: 870.1250
Class: II
Classification Panel: Cardiovascular Percutaneous catheter

Predicate Devices: Substantial equivalence to the following predicates is claimed:

1. ***FilterWire EZ*™** Embolic Protection System; Boston Scientific, cleared under 510(k) number **K063313.**
2. ***AngioGuard RX*** Emboli Capture Guide wire System, Cordis Corporation, a Johnson & Johnson Company, cleared under 510(k) number **K101651.**

Device Description:

WIRION™ is a embolic protection System comprised of an independent Filter Unit that can be delivered, locked and deployed on commercially marketed guide wires, according to physician preference, anywhere on the wire. The WIRION™ is a rapid exchange system for single use by a single operator.

Indication for Use Statement:

The WIRION™ is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries.
The diameter of the vessel at the site of filter basket placement should be between 3.5 mm to 6.0 mm. WIRION™ may be used with commercially available 0.014" guide wires.

Technological characteristics and Substantial Equivalence:

A comparison between the WIRION™ Embolic Protection System and its predicates was performed in order to support substantial equivalence determination.
The substantial equivalency was concluded based on the device's intended use, system components, functional characteristics, principle of operation, technological characteristics, sterilization, materials and biocompatibility.
The conclusion of the comparison analysis is that the WIRION™ Embolic Protection System is Substantially Equivalent to the predicate devices.

Performance Testing:

Clinical and non-clinical tests were conducted. The appropriate tests performed in order to determine substantial equivalency were completed.
These include testing in accordance with FDA Guidance for coronary and carotid embolic protection devices – premarket notification submissions (February 15, 2008) and additional tests as determined during WIRION™'s V&V activities. All tests met their predetermined acceptance criteria and the device was found substantially equivalent to the predicate devices for its intended use.

Non-clinical Data:

The following tests have been performed:

- **a)** Embolic Capture Efficiency and Retrieval Ability
- **b)** Stent Compatibility
- **c)** Simulated Use
- **d)** Resistance to filter rupture during removal of a fully loaded filter
- **e)** Flow Characteristics
- **f)** Radial Outward Force
- **g)** Tip Flexibility
- **h)** Tensile Strength
- **i)** Torque Strength and Response
- **j)** Dimensional Verification
- **k)** Catheter Coating Integrity
- **l)** Corrosion Resistance
- **m)** Fatigue
- **n)** Radio-opacity
- **o)** EtO Sterilization Validation for at least SAL 10-6.

p) Shelf Life/Package Integrity Tests
q) Biocompatibility according to ISO 10993-1:2009 and FDA Blue Book Memorandum, G95-1.

Animal Data:
Two animal studies were conducted using swine model.
Safety parameters such as vessel injury, thrombus formation, neurological effects, device integrity and hemolysis were evaluated.
Performance parameters including usability, navigation, delivery, placement and retrieval of the system and the ability to capture embolic particles were evaluated as well. The device performed comparably to the predicate device. The animal studies results support the substantial equivalence of the WIRION EPS.

Clinical Data

Clinical data from the WIRION™ was collected from clinical studies and commercial use.
Open label single arm feasibility study aimed at demonstrating the safety and performances of the device used during treatment of carotid artery lesions undergoing stenting was conducted.
The WISE study: Multicenter non-randomized prospective, open label, single arm study with comparison to historic control was conducted on 120 patients.
The primary endpoint was MACCE rate and the secondary endpoint evaluated the device performances.
The data demonstrated that the observed MACCE rate was 3.3% while the MACCE rate of the historic control was 6.3%. The obtained P value was 0.0008, less than the 0.0015 which is the performance goal of the study thus the WIRION system met the primary end point.
Secondary endpoint (performances) included device success, clinical success, access site complications, angiographic and procedural success rate. All functions had high success rate of more than 95%. The endpoints related to incidents and complications, were low resulting in 1.7% and 4.1% as summarized below: Device success: 99.2%; Clinical success: 97.5%; Angiographic success: 99.2%; Procedural success: 98.3%; Access site complications: 1.7%; Neurological events: 4.1%. The device performed well and met all specifications and intended use requirements therefore secondary endpoint was met as well.

Conclusions:
The evaluation of the WIRION™ Embolic Protection System performance tests and biocompatibility studies demonstrated that the device performs as intended and that it is as safe and as effective as the predicate devices.
In light of the above, we believe it is substantially equivalent to the FilterWire EZ™ Embolic Protection System (K063313) and to the AngioGuard RX Emboli Capture Guidewire System (K101651) and that it is appropriate for its intended use.